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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,943	11/17/2005	Rango Dietrich	27010U	3568

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
07/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,943	DIETRICH ET AL.	
	Examiner	Art Unit	
	ERIC E. SILVERMAN	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-13-06,1-5-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending pursuant to the amendment filed 10/4/2005. All claims are examined on the merits in this action.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 14, 15, 20-22, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10555331. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims do not require the specific active of copending claims, but the active of copending claims is an APA, thus reading on instant claims. Not all of copending claims require the excipients of instant claims, but copending claim 16 requires sodium carbonate, crospovidene (disintegrating agent), fillers, and diluents. While copending claims do not recite

immediate release, they have the same components as instant claims and thus there is a basis to conclude that they have the same properties

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-16, and 20-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-46 of copending Application No. 11/349969. Although the conflicting claims are not identical, they are not patentably distinct from each other because while instant claims do not specify the APA, copending claims are limited to particular APAs. Further, while copending claim 20 does not require a basic ingredient and other excipients of instant claims, dependant copending claims include these limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-16, and 20-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-27, 34, 37 and 38 of copending Application No. 10433304 in view of US 6,299,904. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending claims do not specifically call for a basic compound, but do call for all the other required excpients. US '904 teaches that basic compounds are used in conjunction with acid unstable drugs, such as proton pump inhibitors, to stabilize them. Col 6-7.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 13, 14, 15, 22, and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 7,357,943. Although the conflicting claims are not identical, they are not patentably distinct from each other because while instant claims do not require a suspension, patented claims do; this makes patented claims a species of instant claims in this respect. While copending claim 1 does not require the specific ingredients of instant dependant claims, other patented claims recite these ingredients.

Claims 1-16, and 20-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,147,869. Although the conflicting claims are not identical, they are not patentably distinct from each other because while instant claims do not require the matrix of patented claims; this makes patented claims a species of instant claims. While patented claim 1 does not require the excipients of instant dependent claims, other patented claims recite these excipients.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This claim lists "aromas" as a type of excipient. An aroma is not an excipient, or even a type of chemical compound. Did Applicants' intend to recite "excipients that have aromas," or something of that sort?

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16, and 20-25 rejected under 35 U.S.C. 102(b) as being anticipated by US 4,786,505 to Lovgren et al. (cited on IDS filed 1/15/2006).

Lovgren discloses dosage forms of omeprazole, a proton pump inhibitor. In Example 2, the composition includes the drug, lactose (filler/dilluent), microcrystalline and cellulose (filler/diluent) disodium hydrogen phosphate (basic compound), and mannitol (flavoring/sweetener) and is in the form of uncoated or coated pellets. In Examples 9 and 10, the dosage form is in the form of coated or uncoated tablets, and includes the drug, crosslinked polyvinylprrolidone (a rapid disintegration excipient), lactose (filler/dilluent), sodium carbonate (basic compound), crosslinked polyvinyl pyrrolidone (rapid disintegration excipient) and magnesium stearate (lubricant). While the reference does not disclose the release rates, because the dosage forms have a rapid release excipient, and also have the same composition as instant claims, there is a basis to conclude that they inherently possess the immediately release characteristics of instant claims (at least in embodiments where they are not enterically coated). Indeed, the subcoat is described as being soluble to water, and the core as rapidly disintegrating. Col. 3. The method of making is disclosed, and involves mixing the various ingredients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-15, 14-20, and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/45693 ("WO '693") (cited on IDS filed 1/5/2006).

WO '693 teaches rapidly disintegrating tablets. Page 44 *et seq*. Fur the purposes of it's disclosure, WO '693 defines rapidly disintegrating tablets as those that release active in 60 seconds or less. Page 46. Rapidly disintegrating tablets contain filers, such as sodium carbonate and microcrystalline cellulose, disintegrants such as sodium carboxymethyl starch, and lubricants such as magnesium stearate. Page 44-45. Flavoring substances may also be added. Page 45. The tablets are formed by

steps comprising mixing all of the materials. *Id.* The formulation is useful for a wide variety of drugs; one exemplified drug is the drug of instant claims 17-19 and 26. Examples 27-29.

WO '693 does not teach all of the required ingredients together in a single embodiment.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to make the immediate release tablets of instant claims. The teachings of the prior art show that the claims represent no more than the combination of known immediate release excipients with a drug known to be useful with such excipients to form an immediate release composition. Use of these known ingredients for their art-recognized purpose is grounds for a holding of obviousness.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lovgren in view of WO '693.

The teachings of Lovgren were discussed above.

What is lacking is the drug of instant claims.

WO '693 teaches the drug of instant claims 17-19 and 26 as a proton pump inhibitor. Page 34 *et seq*.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to substitute the drug of claims 17-19 and 26 for omeprazole of Lovgren. The two drugs are taught in the art as serving the same purpose, and are structurally related. It is generally obvious to substitute two materials that are recognized in the art as serving the same purpose to achieve that very purpose. Here,

both drugs are recognized as APA inhibitors that can be used in rapid-release tablets or dosages.

Conclusion

No claims are allowed

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,299,904 (cited on IDS filed 1/5/2006) at col. 6-7 teaches that addition of a basic salt, such as sodium carbonate, is a known way to stabilize an acid-labile drug. The exemplified acid unstable drugs are proton pump inhibitors. Thus, contrary to the statement on page 3 of Applicants' specification, a finding that a proton pump inhibitor forms a stable composition when mixed with a basic excipient would not have surprising to the artisan as of the filing date of this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618